

Remarks

Claims 45-56 are pending in the application.

I. Rejection of the Claims Under 35 U.S.C. § 112, second paragraph

Claims 45-56 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. (Office Action, page 2.) The Examiner asserts that in claim 45 it is not clear what is meant by the term “present *in trans*” in that what *in trans* is relative to is unclear. Applicants have amended claim 45 to recite “the packaging signal of the first nucleic acid molecule is present *in trans* with respect to the at least three additional nucleic acid molecules which encode retroviral proteins” to clarify this point. Support for this amendment can be found in Example 9, in particular paragraph [0626] which recites “[t]hree supercoiled packaging plasmids (gag/pol, rev and VSV-G envelope) are provided to supply helper functions and viral proteins in *trans*.” And further, in paragraph [0629], which recites “[s]imilar to other retrovirus expression systems, the packaging functions of HIV can be supplied in *trans*.”

In view of the above, Applicants assert that the present claims meet the requirements of 35 U.S.C. § 112, second paragraph and respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

II. Rejection of the Claims Under 35 U.S.C. § 112, first paragraph

Claims 45-56 stand rejected under 35 U.S.C. § 112 first paragraph as failing to comply with the enablement requirement. (Office Action, page 4.) Applicants respectfully disagree.

The Examiner asserts that Example 9 does not describe a packaging signal provided *in trans*. (Office Action, page 4.) Applicants respectfully point to paragraphs [0650-0653] which describe the features of the four plasmids used in the Example. The vectors pLenti6/V5-DEST and pLenti6/V5-D-TOPO contain the psi packaging signal (paragraph [0650]). The remaining three plasmids, pLP1, pLP2 and pLP/VSVG provide gag/pol, rev and VSV-G genes respectively, all *in trans*. Therefore, in Example 9, the psi packaging signal is provided on a separate plasmid from the viral proteins and is clearly present *in trans* as presently claimed.

Claims 45-56 stand rejected under 35 U.S.C. § 112 first paragraph as failing to comply with the written description requirement. (Office Action, page 5.) Applicants respectfully disagree.

The Examiner asserts that the instant specification provides no teaching to support providing a packaging signal *in trans* in the construction of a replication-incompetent recombinant retrovirus. As discussed above, support for a packaging signal provided in trans along with other viral proteins is present at least in paragraphs [0649-0653] of Example 9. Applicants believe that the present claims are fully described and supported by the specification.

In view of the above, Applicants assert that the present claims are fully described and enabled by the specification and respectfully request reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 112, first paragraph.

Conclusion

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

/Peter G. Foiles/
Registration No. 46,477
Peter G. Foiles
Agent for Applicants
(240) 379-4173

Date: June 28, 2010